K010034

Special 510(k) Premarket Notification: Modified Device
Double Lumen Urethane PICC Line
COOK INCORPORATED

JAN 2 4 2001

Safety and Effectiveness Information

Submitted By: Lisa Webb, RAC
Regulatory Affairs Coordinator
COOK INCORPORATED
925 South Curry Pike
P.O. Box 489
Bloomington, IN 47402
(812) 339-2235
January 3, 2001

Device: Trade Name: Double Lumen Urethane PICC Line

Proposed Classification Name: Intravascular Catheter

Predicate Devices:

The Double Lumen Urethane PICC Line is similar in terms of intended use, materials of construction, and technological characteristics as the predicate devices reviewed: COOK® Single Lumen Urethane PICC Lines, COOK® Silicone PICC Lines, Arrow International PICC Lines, and Vaxcel™ PICC Lines.

Device Description:

The Double Lumen Urethane PICC Line is comprised of five components which can be further described as follows:

- Catheter: The catheter is constructed of Urethane and is available in a 5 Fr double lumen configuration. The catheter is 60 cm in length.
  - The distal end of the catheter tubing has depth distance markers in 5 cm increments. The final 5 cm (from the 55 cm mark to the winged manifold) are designed as a bump tubing.
  - The proximal end configuration is composed of a winged manifold, extension tubing, and a luer lock hub which are discussed below.
- Winged Manifold: The winged manifold is constructed of Urethane.
- Extension Tubing: The extension tube is constructed of Urethane.
- Clamp: A plastic clamp is provided around the external surface of each of the extension tubes.
- Luer Lock Hub: The luer lock hubs are constructed of Urethane and are stamped on both sides as follows. The large lumen is stamped ".62CC LUM VOL." The small lumen is stamped ".60CC LUM VOL."

The Double Lumen Urethane PICC Line will also be available in a set or tray that incorporates legally marketed accessories. These accessories are identical to those currently sold in the company's Single Lumen Urethane PICC Line and Silicone PICC Line sets and trays.

Substantial Equivalence:

Four devices are currently marketed which are believed to be substantially equivalent to the Double Lumen Urethane PICC Line, subject of this submission. These devices include Single Lumen Urethane PICC Lines (COOK®), Silicone PICC Lines (COOK®), Peripherally Inserted Central Catheters (Arrow International), and Vaxcel™ PICC Lines (Boston Scientific/Medi-Tech®).

Test Data

The Double Lumen Urethane PICC Line has been subjected to and has passed the following tests to assure reliable design and performance under the specified testing parameters. These tests include:

- Tensile testing
- Flow testing
- Burst testing
- Liquid leakage testing
- Air leakage testing
- Stability Testing
- Flexibility Testing

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 4 2001

Ms. Lisa Webb
Regulatory Affairs Coordinator
Cook, Incorporated
P.O. Box 489
925 South Curry Pike
Bloomington, Indiana 47402-0489

Re: K010034
Trade Name: Double Lumen Urethane PICC Line
Regulatory Class: II
Product Code: FOZ
Dated: January 3, 2001
Received: January 4, 2001

Dear Ms. Webb:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Special 510(k) Premarket Notification: Modified Device
Double Lumen Urethane PICC Line
COOK INCORPORATED

510(k) Number (if known): K010034

Device Name: Double Lumen Urethane PICC Line

Indications for Use:

Used for venous pressure monitoring, blood sampling and administration of drugs and fluids.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010034